K080227

MAY 15 2008

# 510(k) Summary: ACCU-CHEK® 360° Diabetes Management System

**Introduction**

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**Submitter name, address, contact**

Roche Diagnostics
9115 Hague Rd.
PO Box 50457
Indianapolis, IN 46250
Contact Person: Scott Thiel

**Device Classification**

Trade Name: ACCU-CHEK® 360° Diabetes Management System
Common Name: diabetes management software
Classification Name: calculator/data processing module for clinical use
Classification Regulations: 880.5725, 862.1345, 862.2100
Product Codes: LZG, LFR, JQP

**Predicate Device(s)**

We claim substantial equivalence of the ACCU-CHEK 360° Diabetes Management System to the current legally marketed Camit Diabetes Management Software (K001907) and Smart Pix Device Reader (K062395).

**Device Description**

Software accessory to ACCU-CHEK® brand meters and/or Disetronic/ACCU-CHEK insulin infusion pumps.

**Indications for Use Statement**

The ACCU-CHEK® 360° Diabetes Management System is indicated for use by individuals or healthcare professionals in the home or health care facilities to support effective diabetes management. The software also allows for entry of other healthcare parameters with or without diabetes related information, which can be shown in report and graphical format. This device is indicated for professional use and over-the-counter sale.

*Continued on next page*

# 510(k) Summary: ACCU-CHEK® 360 Diabetes Management System, Continued

**Similarities and Differences**

The following tables provide a listing of product similarities and differences between the ACCU-CHEK® 360° Diabetes Management System and the predicate devices: ACCU-CHEK® Camit Diabetes Management Software and ACCU-CHEK® Smart Pix.

| ACCU-CHEK® 360° | Camit | Smart Pix |
|---|---|---|
| Downloads device memory from ACCU-CHEK blood glucose monitors. | Yes | Yes |
| Downloads device memory from ACCU-CHEK insulin infusion pumps. | No | Yes |
| Generates reports and basic statistics to support retrospective data analysis. | Yes | Yes |
| Generates reports using retrospective data from both blood glucose monitors and insulin infusion pumps. | No | Yes |
| Uses activation key to establish which program functionality is made available to the end user. | No | No |
| Compatible with Microsoft XP Operating System (OS). | Yes | Yes |
| Support through ACCU-CHEK Customer Care | Yes | Yes |
| Data storage on computer media | Yes | Yes |
| Track non-blood glucose data (e.g. carbohydrates, insulin, time blocks, event codes) | Yes | Yes |
| On-line help | Yes | No |
| Ability to support multiple patients in the same database | Yes | No |
| Password protection | Yes | No |
| Allows for manual entry of data | Yes | No |

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# 510(k) Summary: ACCU-CHEK® 360 Diabetes Management System, Continued

**Similarities and Differences** (continued)

| ACCU-CHEK® 360° | Camit | Smart Pix |
|---|---|---|
| Security through secure socket layer protocol with 128-bit encryption. Reliance upon user to maintain security of user id and password. | Yes | Yes |
| User has option of sending reports via email, printing, or viewing on screen | User has option of reviewing on screen or printing. | User has option of reviewing on screen or printing. |
| On-line help, tour, getting started guide, frequently asked questions (FAQ). | Yes | Yes |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

Mr. Scott Thiel
Regulatory Affairs Program Manager
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, Indiana 46250

Re: K080227
Trade/Device Name: ACCU-CHEK® 360° Diabetes Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: May 1, 2008
Received: May 2, 2008

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K080227

Device Name: ACCU-CHEK® 360° Diabetes Management System

Indications for Use:

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Prescription Use ___XX__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __XX_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



510(k) Number: K080227